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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/728,679 | 12/05/2003 | Jerry R. Colca | 01012/1 | 9803 |

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| EXAMINER | |
|---|---|
| CHANDRA, GYAN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/728,679 | COLCA ET AL. | |
| | Examiner | Art Unit | |
| | Gyan Chandra | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Note: After a discussion with attorney on 13 February 2006 and subsequent review of the instant claims, the Examiner has determined that the restriction should be done according to 35 U.S.C. 121 Restriction practice and not as per 35 U.S.C. 372. Therefore, the Restriction requirement of 15 November 2005 is hereby vacated. For Applicant's records, please use the mail date of the current office action.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a method of identifying a compound for the treatment, prevention or diagnosis of a mitoNEET associated dysfunctional disease or condition comprising the steps of determining a direct interaction of compound with mitoNEET, classified in class 435, subclass 7.2.

II. Claims 8-10, drawn to a method of treating or preventing a mitoNEET associated a metabolic dysfunctional disease or condition comprising administering a compound that directly interacts with mitoNEET, classified in class 514, subclass 2.

III. Claim 11, drawn to an antibody that immunospecifically binds the mitoNEET polypeptide, classified in class 530, subclass 387.1.

IV. Claim 12, drawn to a method of detecting a differentially expressed gene correlated with a mitoNEET associated metabolic dysfunctional disease or condition of a mammalian cell, classified in class 435, subclass 6.

V. Claim 13, drawn to a method of monitoring the progression of a metabolic disorder in a patient comprising detecting the expression of a marker at a first point in time in a patient and then compare the expression of the marker at a subsequent point in time, classified in class 435, subclass 6.

VI. Claim 14, drawn to a method of assessing the efficacy of a test compound for correcting the metabolic disturbance comprising comparing the expression level of a marker in a sample obtained for a patient after administering a test compound with the expression level of the marker in a second sample from the patient without administering the test compound, classified in class 514, subclass 9.2.

VII. Claim 15, drawn to a method of selecting a compound for treating, preventing or diagnosing a mitoNEET associated metabolic dysfunctional disease or condition in a patient that alters the level of a marker expression most, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons: Inventions I, II, IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of identifying a compound for the treatment, prevention or diagnosis of a mitoNEET associated dysfunctional disease or condition (group I), the method of

treating or preventing a mitoNEET associated a metabolic dysfunctional disease or condition comprising administering a compound that directly interacts with mitoNEET (group II), the method of detecting a differentially expressed gene correlated with a mitoNEET associated metabolic dysfunctional disease or condition of a mammalian cell (group IV), the method of monitoring the progression of a metabolic disorder in a patient comprising detecting the expression of a marker at a first point in time in a patient (group V), the method of assessing the efficacy of a test compound for correcting the metabolic disturbance comprising comparing the expression level of a marker in a sample obtained for a patient after administering a test compound with the expression level of the marker in a second sample from the patient without administering the test compound and then compare the expression of the marker at a subsequent point in time (group VI), and the method of selecting a compound for treating, preventing or diagnosing a mitoNEET associated metabolic dysfunctional disease or condition in a patient that alters the level of a marker expression most (group VII) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using different steps. For these reasons the Inventions I, II, IV, V and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I, II, IV, V and VI would require special disease limitation search using NPL, and other databases. As such, it would be burdensome to search the inventions of Groups I, II, IV, V and VI together.

Inventions III and I, II, IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated. For example, the claimed methods I, II, IV, V and VI does not recite the use of a polypeptide (antibody) from Group III.

Furthermore, the inventions of Groups III and I, II, IV, V and VI require separate, distinct and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups III and I, II, IV, V and VI together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and separate search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra, Ph.D.
Art Unit 1646
06 March 2006
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JANET L. ANDRES
SUPERVISORY PATENT EXAMINER